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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,997

07/11/2003

Stephane Bibian

B564 0001

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08/01/2006

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,997

Applicant(s)

BIBIAN ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 24-25, 29, 36 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/11/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 24, 25, 29, and 36 are objected to because of the following informalities:

In claim 24, line 1 states “the method of claim 25” – for clarity, it is suggested that this be changed to --the method of claim 23--. For examination purposes, it will be treated as such.

In claim 25, line 1 states “the method of claim 25” – for clarity, it is suggested that this be changed to --the method of claim 23--. For examination purposes, it will be treated as such.

In claim 29, line 1 states “the method of claim 30” – for clarity, it is suggested that this be changed to --the method of claim 28--. For examination purposes, it will be treated as such.

In claim 36, line 1 states “the computer program of claim 35” – for clarity, is suggested that this be changed to --the computer program product of claim 33--. For grammatical accuracy, it is suggested that --a-- be added between “and” and “data processor.” Additionally, since claims 34-35 are not present, it is suggested that this claim be renumbered as claim 34 to properly continue the sequence of claims. For examination purposes, the claim will be treated as such.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

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2. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 7-10, 12-18, 23, 25, 28-29, 32-33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by John'467 (US Patent 6067467).

Regarding claim 1, John'467 discloses a method comprising acquiring a plurality of reference signals that correspond to CNS states (column 2, lines 59-60); selecting a transformation function to apply to signals (column 4, lines 61-62); selecting a statistical function to apply to the results of the transformation function to yield a reference data set that characterizes the patient's CNS state (column 4, lines 63-67); applying the transformation and statistical functions to the reference signals (column 4, lines 61-67); capturing a real-time brain signal from brain activity (column 5, lines 7-9); applying the transformation and statistical functions to the real-time signal (column 5, lines 8-10); comparing the real-time data to the reference data (column 5, lines 9-10); and computing a numerical value representative of the patient's CNS state based upon the comparison (column 3, lines 55-67; column 9, line 48 to column 10, line 10).

The examiner notes that John'467 does not specifically disclose that the transformation function yields coefficients, or the application of a statistical function to the coefficients. However, the application of a transformation function

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to data inherently yields results that include coefficients, which would subsequently be treated by the statistical function that is applied to the results of the transformation function.

Regarding claim 2, John'467 further discloses that the signals are electroencephalograms (EEG's) (column 2, lines 41-43).

Regarding claim 3, John'467 further discloses that the observed signal comprises a plurality of EEG's (column 4, lines 26 and 51-52).

Regarding claim 4, John'467 further discloses that the reference subject or subjects may be persons other than the patient (column 3, lines 57-58).

Regarding claim 5, John'467 further discloses that the statistical function is one of group histogram, probability density, standard deviation, or variance (column 4, line 63).

Regarding claim 7, John'467 further discloses that the method is used to measure a patient's level of consciousness (column 3, lines 60-64).

Regarding claim 8, John'467 further discloses that the method is used to measure a patient's level of hypnosis (column 3, lines 42-46).

Regarding claim 9, John'467 further discloses that the method is used to measure the effects of anesthesia upon a patient (column 2, lines 41-43, 57-55, and 64-67).

Regarding claim 10, John'467 further discloses that the method is used to measure the effects of psychoactive medicaments upon a patient (column 2, lines 41-43, 57-55, and 64-67), since anesthesia is a psychoactive drug.

Regarding claim 12, John'467 further discloses using the method to determine titration and dosage profiles of neurologic and psychoactive compounds and medicaments (column 15, lines 37-57), since anesthesia is a psychoactive drug.

Regarding claim 13, John'467 further discloses that the method may be used to monitor the level of brain ischemia (column 1, lines 53-57).

Regarding claim 14, John'467 further discloses that the method may be used to measure neurological activity in a subject (column) to ascertain the effects of neurologic and psychoactive compounds and medicaments on the patient's brain (column 2, lines 41-43, 57-55, and 64-67), since anesthesia is a psychoactive drug.

Regarding claim 15, John'467 further discloses that the CNS states represent distinct states on the continuum between conscious and no brain activity (column 9, lines 52-66).

Regarding claim 16, John'467 further discloses that the distinct CNS states are chosen from among sedation, light anesthesia, deep anesthesia, and no brain activity (column 9, lines 55-65).

Regarding claim 17, John'467 further discloses that the distinct states are two distinct states (column 10, lines 16-18).

Regarding claim 18, John'467 further discloses that the two distinct states are fully conscious (awake) and no brain activity (unconscious) (column 10, lines 16-18).

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Regarding claim 23, John'467 further discloses that the transformation function is a filter with frequency response to yield coefficients of brain activity in a specific frequency band (column 5, lines 49-55).

Regarding claim 25, John'467 further discloses that the at least one frequency band is chosen so that the statistical representation of its data differentiates between CNS states (column 8, lines 58+).

Regarding claim 26, John'467 further discloses that the comparison is done by computing the correlation between the observed and reference data sets (column 9, lines 19-40).

Regarding claim 28, John'467 further discloses that the result of the comparison is a number of values (column 9, lines 25-34).

Regarding claim 29, John'467 further discloses that the values are combined into a value indicative of the patient's CNS state (column 9, lines 50-65).

Regarding claim 32, John'467 discloses a system comprising a sensor for observing the electrical brain activity of a subject to produce a signal (column 4, lines 24-26; and column 5, lines 7-9); and a digital signal processor for applying a transformation function that yields coefficients to a reference signal (column 4, lines 61-62), for applying a statistical function that yields data sets to the reference signal coefficients (column 4, lines 63-67), for applying the transformation and statistical function to the observed brain signals (column 5, lines 8-10), for comparing the observed and reference data sets (column 5, lines 9-10), and for computing a numerical representation of the subject's CNS state

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based on the comparison's results (column 3, lines 55-67; column 9, line 48 to column 10, line 10).

Regarding claim 33, the computer-operated method of John'467 described above in reference to claim 1 inherently has a computer program product comprising a computer usable medium having computer readable program code embodied within.

Regarding claim 36, John'467 further discloses the presence of a data processor (elements 16 and 21; column 5, lines 53-55).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Tarassenko'857 (US Patent 7031857).

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John'467 discloses all the elements of the current invention, as applied to claim 1, except for the statistical function being a probability density function.

Tarassenko'857 teaches a method of analyzing signals from a patient, including brain signals, comprising calculating a probability density function (column 9, lines 26-29 and 66-67), so that the patient's condition may be better indicated to an observer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and, when applying a statistical function, used a probability density function, as taught by Tarassenko'857, so that the patient's condition may be better indicated to an observer.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Viertio-Oja'291 (US Patent 6631291).

John'467 discloses all the elements of the current invention, as applied to claim 1, except for using the method to measure neurological activity in order to obtain pharmacodynamic and pharmacokinetic models of neurologic and psychoactive compounds and medicaments.

Viertio-Oja'291 teaches a method of monitoring brain signals (column 2, lines 37-38) and using the data to establish pharmacodynamic and pharmacokinetic models of drug effects (column 11, lines 17-28), so that a patient's treatment is more stringently controlled.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used the data to establish pharmacodynamic and pharmacokinetic models of the effect of an administered treatment, so that a patient's treatment may be more stringently controlled.

8. Claims 19, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Lesser'685 (US Patent Application Publication 2003/0171685).

Regarding claim 19, John'467 discloses all the elements of the current invention, as applied to claim 1, except for the transformation function being a wavelet transform.

Lesser'685 teaches a method of analyzing brain signals comprising performing wavelet transform (paragraph [0027]), in order to improve the signals' resolution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and performed wavelet transform, as taught by Lesser'685, in order to improve the quality of captured signals.

Regarding claim 22, John'467 discloses all the elements of the current invention except for the transformation function being a transform with both time and frequency localization features.

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Lesser'685 teaches a method of analyzing brain signals comprising performing a transform with both time and frequency localization features (paragraph [0027]), in order to improve the signals' resolution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and performed a transform with both time and frequency localization features, as taught by Lesser'685, in order to improve the quality of captured signals.

Regarding claim 24, John'467 discloses all the elements of the current invention, as applied to claim 23 above, except for the transformation function filter being a wavelet filter.

Lesser'685 teaches a method of analyzing brain signals comprising performing a transform using a wavelet filter (paragraph [0033]), in order to improve the signals' resolution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and performed wavelet transform, as taught by Lesser'685, in order to improve the quality of captured signals.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Tarassenko'857, as applied to claim 6 above, and further in view of Lesser'685.

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John'467 in view of Tarassenko'857 discloses all the elements of the current invention, as applied to claim 6 above, except for the transformation function being a wavelet transform.

Lesser'685 teaches a method of analyzing brain signals comprising performing wavelet transform (paragraph [0027]), in order to improve the signals' resolution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 in view of Tarassenko'857, and performed wavelet transform, as taught by Lesser'685, in order to improve the quality of captured signals.

10. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Lewis'611 (US Patent 5762611).

Regarding claim 30, John'467 discloses all the elements of the current invention, as applied to claims 1-5, 7-10, 12-18, 23, 25, 28-29, 32-33, and 36 above, except for the method using a single-channel EEG to provide the signals.

Lewis'611 teaches that a single-channel EEG may be used to provide brain signal data (column 8, lines 44-48), in order to appropriately match the data capture system to the type of data being captured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used an single-channel EEG to capture the data as taught by Lewis'611, in order to appropriately match the data capture system to the type of data being captured.

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Regarding claim 31, John'467 discloses all the elements of the current invention, as applied to claims 1-5, 7-10, 12-18, 23, 25, 28-29, 32-33, and 36 above, except for the method using a multiple-channel EEG to provide the signals.

Lewis'611 teaches that a multiple-channel EEG may be used to provide brain signal data (column 8, lines 44-48), in order to appropriately match the data capture system to the type of data being captured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used an multiple-channel EEG to capture the data as taught by Lewis'611, in order to appropriately match the data capture system to the type of data being captured.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5775330 to Kangas, which discloses a method and apparatus for collection and analysis of EEG data.

US Patent 5699808 to John, which discloses a method and apparatus for collection and analysis of EEG data.

US Patent 4862359 to Trivedi, which discloses a method and apparatus for collection and analysis of EEG data.

US Patent 5010891 to Chamoun, which discloses a method and apparatus for collection and analysis of EEG data.

US Patent 6016444 to John, which discloses a method and apparatus for collection and analysis of EEG data.

US Patent 6317627 to Ennen, which discloses a method and apparatus for collection and analysis of EEG data.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "Robert L. Nasser". The signature is fluid and cursive, with a long horizontal stroke at the end.

ROBERT L. NASSER
PRIMARY EXAMINER